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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,102	12/27/2004	Imao Mikoshiba	Q85257	9490

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,102	MIKOSHIBA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 08, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14,24 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14,24 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 08, 2008 has been entered.

Applicants' arguments, filed December 08, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Amendment

The declaration by Yuji Kiyono under 37 CFR 1.132 filed December 08, 2008 has been considered but is not found persuasive because the study cited in the declaration used healthy volunteers, which would mean none of the patients studied fit the patients of the claims which require a type II human diabetic patient. Diabetic patients would clearly have a different response to sugar, have different postprandial blood sugar levels and reactions, and would also be expected to react to medication or treatments

differently and thus the declaration submitted by applicant has no bearing upon the present invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 34-36 applicant claims "a method as claimed in claim 12, which comprises administering three times a day". It is unclear what applicant is claiming as the language "which comprises" implies that the method of claim 12 contains the three times per day administration which it does not. Additionally the language "administering three times a day" is unclear as to what is being administered or who it is being administered too. Thus one of skill in the art would not be able to determine what is being administered to whom and thus claims 34-36 are rejected for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14, 24, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa et al. (Clinical and Experimental Pharmacology and Physiology, 2002, vol. 29, pages 423-427).

In claims 12 and 14, applicant claims a method for lowering postprandial blood glucose levels comprising administering to a type II human diabetic patient, within 10 minutes before starting a meal, 10-11 mg of mitiglinide calcium salt hydrate. As mentioned on pages 6-7 of the office action mailed July 13, 2007, KAD-1229 is mitiglinide calcium salt hydrate. Ichikawa et al. teaches using KAD-1229 to control postprandial hyperglycemia (page 423, summary). They further teach that the rats tested were fasted, then given the KAD-1229 orally and immediately given a liquid meal (page 424, third paragraph). Immediately is within 10 minutes, which is the time frame

claimed by applicant. They also teach dosages of 0.3-3 mg/kg (page 424, table 1). Ichikawa et al. is treating type 2 diabetic rats, which are used as an animal model and it would have been obvious to one of ordinary skill in the art at the time of the invention to use this method to treat human type 2 diabetic patients as that is the goal of most diabetic research and animal models are commonly used with the goal of finding a treatment for humans. The dosage of 0.3-3 mg/kg, in a 120lb (55kg) patient would be a range of 16-165mg. While 16 mg is still larger than 10-11 mg claimed, some routine optimization is well within the skills of one of ordinary skill in the art and in translating dosages from rats to humans one would expect some variation and need to optimize. Furthermore there is a motivation to use as small of a dosage as possible that is still effective in humans to decrease the side effects. Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg/day dosage amounts, such a motivation is nonetheless relevant. Thus claims 12 and 14 are unpatentable over Ichikawa et al.

In claim 24, applicant claims the method of claim 12, wherein the patient is a human patient whose HbA_{1C} value is not less than 6.5% and the 1 hour or 2 hour value of postprandial plasma glucose is not less than 200 mg/dL, even after more than 8 week diet therapy. Applicant has claimed a very specific patient, and although Ichikawa et al.

does not disclose that HbA_{1C} values and postprandial values after 8 weeks of diet therapy the patient in claim 24 is a type 2 diabetic patient and one which it would be obvious to one of ordinary skill in the art at the time of the invention that would benefit from treatment with KAD-1229 as taught by Ichikawa et al. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Ichikawa et al. to treat such a patient and claim 24 is also unpatentable over Ichikawa et al.

In claims 34-36 applicant claims the method of claim 12 which comprises administering three times a day within 5 minutes before starting a meal for 4 weeks or more. As discussed above Ichikawa et al. teaches giving KAD-1229 immediately before a meal, and since most humans eat three meals per day it would be obvious to one of ordinary skill in the art to administer it with each meal. Additionally, since type 2 diabetes is an ongoing condition and most treatments are continued indefinitely it would also have been obvious to one of ordinary skill in the art at the time of the invention to continue the treatment of Ichikawa et al. for more than 4 weeks. Thus claims 34-36 are also unpatentable over Ichikawa et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614